AUG 1 0 2001

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

K012389

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (262) 544-3894
Summary prepared: 25 June 2001

Identification of Product: Revolution XR/d Digital Radiographic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Device Description: The Revolution XR/d Digital Radiographic Imaging System is designed to perform radiographic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing, and storage. The Revolution XR/d Digital Radiographic Imaging System consists of an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, collimator, system controller, generator, and tilting radiographic wall stand with integrated digital detector. The configuration can consist of digital table and digital wall stand, digital table only, or digital wall stand only.

Indications for Use: The Revolution XR/d Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with: The Revolution XR/d Digital Radiographic Imaging System is an enhanced version of and substantially equivalent to the

Revolution XR/D Digital Radiographic Imaging System, originally cleared in K992066.

Conformance:

The Revolution XR/d Digital Radiographic Imaging System will conform to applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL 2601-1, IEC 601-1, IEC 601-1-2, and IEC 601-1-3.

Conclusions:

In the opinion of GE Medical Systems, the Revolution XR/d Digital Radiographic Imaging System is substantially equivalent to the presently marketed Revolution XR/D Digital Radiographic Imaging System (K992066). The Revolution XR/d Digital Radiographic Imaging System does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

GE Medical Systems, Inc.
% Mr. Reiner Krumme
Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K012389
Revolution XR/D Digital Radiographic Imaging System
(Radiographic x-ray system with SSXI)
Dated: July 23, 2001
Received: July 27, 2001
Regulatory Class: II
21 CFR 892.1630/Procode: 90 MQB
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): K012389

Device Name: Revolution XR/d Digital Radiographic X-ray System

Indications for Use

The Revolution XR/d Digital Radiographic X-ray System is indicated for use in generating radiographic images of human anatomy. It is intended for use in replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012389